REMARKS

FORMAL MATTERS

Applicants acknowledge the withdrawal of the Office Action dated May 4, 2004. *See* Office Action at page 2. Applicants thank the Examiner for the telephone interview of July 13, 2004, during which the Examiner's objections to the disclosure were discussed. Applicants have amended the specification accordingly. Applicants also amended claims 1, 3, 9, 10, and 14. No new matter has been added to the claims by way of these amendments. Applicants canceled claims 2, 11, 15-17, 19-22, and 25. Applicants also added new claims 26-30. Support for new claims 26-30 can be found in the specification at, for instance, page 8, lines 5-14.

Claims 1, 3, 9, 10, 14, and 26-30 are now pending in this application.

PRIORITY

The Examiner stated that a certified copy of Japanese application 2000-52414, to which priority is claimed, has not been filed as required by 35 U.S.C. § 119(b). *See* Office Action at page 3. Applicants note that the present application is a National Stage filing of a PCT and therefore a certified copy of this application was filed with the International Bureau of WIPO. Thus, under PCT Rule 17.2, no designated Office should ask the Applicants for a certified copy. However, the PTO may request a copy from the International Bureau. Applicants therefore respectfully request the Examiner to withdraw this objection.

OBJECTIONS TO THE DISCLOSURE

The Examiner objected to the brief description of drawings, for failing to "refer to panels A-D of Fig. 4 and panels A and B of Fig. 5." Office Action at page 4. Applicants respectfully traverse. As stated in section 608.01(f) of the Manual of Patent Examining Procedure (M.P.E.P.), "[i]f a figure contains several parts, for example, figure 1A, 1B, and 1C, the figure may be described as figure 1." The brief description of the drawings of the present invention refers to figure 4 and figure 5, without specifying any panels or parts. *See* specification at page 24. Therefore, Applicants respectfully request that the Examiner withdraw this objection.

The Examiner objected to the disclosure as allegedly improperly incorporating "essential material (information regarding a PTH/PTHrP type I receptor) in the specification by reference to a foreign patent application." Office Action at page 4. Applicants respectfully traverse. However, merely to expedite prosecution, Applicants amended the specification at page 7 to refer to the sequence of the Type I PTH/PTHrP receptor (SEQ ID NO:76), as the Examiner suggested during the telephone interview of July 13, 2004. Further, Applicants added the sequence of the receptor to the Substitute Sequence Listing. This amendment is accompanied by an attorney affidavit, stating that the amendatory material consists of the same material incorporated by reference in the referencing application and thus no new matter has been added. *See* MPEP § 608.01(p)(2). In light of these amendments, Applicants respectfully request that the Examiner withdraw this objection.

REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

The Examiner stated that the specification was "enabling for a method of treating PTHrP-relat[e]d hypercalcemia, septicemia, and cachexia with an anti-PTHrP antibody." Office Action at page 5. However, the Examiner rejected claims 1-3, 9-11, 14-17, 19-22, and 25 as not providing "enablement for (i) a method of treating any other PTH/PTHrP related diseases with an anti-PTHrP antibody; (ii) a method of treating a PTH/PTHrP related disease with any other substance that binds a ligand of PTH receptor or PTHrP receptor; and (iii) a method of preventing a disease mediated by PTH/PTHrP with a substance that binds a ligand of PTH/PTHrP receptor." *Id.*

Applicants respectfully traverse. Although Applicants believe that these concepts are supported by the specification, Applicants have replaced the phrase "disease mediated by PTH or PTHrP" with "septicemia" in claims 1 and 3 and replaced the word "disease" with "septicemia" in claim 9. Further, Applicants have canceled claims 2, 11, 19, 21, and 25, which do not further limit the claims as amended.

The Examiner also asserts that claims 1-3, 9-11, 14-17, 19-22, and 25 are not enabled because "[t]here are no sufficient directions regarding whether an anti-PTH antibody acts as effectively as an anti-PTHrP antibody in the method of treating any diseases." Office Action at page 8. Applicants respectfully traverse. However, merely to expedite prosecution Applicants deleted the phrase "PTH receptor" from claims 1 and 14. Applicants reserve the right to pursue these embodiments in a separate application. Because the Examiner stated that the specification was enabling for a method of

treating PTHrP-related septicemia with an anti-PTHrP antibody, Applicants request that the Examiner withdraw the enablement rejection.

WRITTEN DESCRIPTION REJECTION

The Examiner rejected claims 1-3, 9-11, 14, 19, 21 and 25 as lacking written description. Specifically, the Examiner alleges that, "other than an anti-PTH or an anti-PTHrP antibody, the instant specification does not provide sufficient description for the substance that binds to a ligand of PTH receptor or PTHrP receptor." Office Action at page 10. Applicants respectfully traverse. However, merely to expedite prosecution, Applicants have replaced the phrase "active ingredient chosen from an agonist or antagonist of binding to a PTH receptor or PTHrP receptor and a substance" in claim 1 with "humanized antibody." Further, Applicants added new claims 26-30, which are directed to a method of treating or preventing septicemia comprising administering to a patient at least one human antibody. Applicants canceled claims 15-17, 20, and 22, as they do not further limit the claims as amended. The Examiner stated that the specification provided written description for the anti-PTHrP and anti-PTH antibodies. *Id.* Applicants therefore assert that the claims, as amended, fulfill the written description requirement and request that the Examiner withdraw this rejection.

REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

The Examiner rejected claims 1-3, 9-11, 14-17, 19-22, and 25 as being "indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." Office Action at page 12. Specifically, the Examiner rejected claim 1 for insufficient antecedent basis for the limitation "a ligand of either receptor."

Id. Applicants have replaced the word "either" with "PTHrP." In light of this amendment, Applicants respectfully request that the Examiner withdraw this rejection.

The Examiner specifically rejected claim 3, because allegedly the specification fails to unambiguously define the phrase "quality of life." Office Action at page 12. Applicants respectfully submit that the method of claim 3 is clear to one of ordinary skill in the art when read in light of the specification. The specification at page 8 defines QOL as follows:

> The term 'QOL' is an abbreviation for 'quality of life' and stands for the quality of life. Cancer patients undergo loss of body weight, anorexia, anemia and pain etc. and so their parameters of QOL are significantly damaged.

In addition, the specification at page 30, first paragraph, lists several QOL parameters that include "body weight, amount of autonomic movement and food consumption." These parameters were evaluated in Example 3, "QOL improving effect of anti-PTHrP antibody in human high PTHrP-related hypercalcemia model animals." *See* specification at pages 29-31. Finally, the section titled "QOL improving agent" at pages 33-34 of the specification discusses the various symptoms that reduce QOL and how the composition of the invention may lead to their improvement. Thus, the specification gives sufficient guidance such that one would understand what is claimed. In light of this evidence, Applicants respectfully request the Examiner withdraw this rejection.

ANTICIPATION REJECTIONS

The Examiner rejected claims 1-3, 9-11, 14-17, 19-22, and 25 as being anticipated under 35 U.S.C. § 102(e) by Sato *et al.* (US2002/0165363 A1). Office Action at page 13. Specifically, the Examiner asserts that "Sato *et al* teach a therapeutic agent for cachexia" and treatment of cachexia. Office Action at page 8. Applicants respectfully traverse. As described above, Applicants have canceled claims 2, 11, 15-17, 19-22, and 25, without prejudice or disclaimer, and therefore the rejection of these claims is moot. Applicants also replaced the phrase "a disease mediated by PTH or PTHrP" with "septicemia" in claim 1, as discussed above. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." M.P.E.P § 2131. Sato *et al.* do not disclose the administration of a PTHrP antibody to treat or prevent septicemia. Therefore, Applicants request that the Examiner withdraw this anticipation rejection of claims 1, 3, 9, 10, and 14.

The Examiner also rejected claims 1-3, 9-11, 14-17, 19-22, and 25 as being anticipated by Grunfeld *et al.* (WO 96/39184). Specifically, the Examiner alleges that Grunfeld *et al.* teach "treatment of systematic inflammatory response syndrome, including septicemia with an anti-PTHrP antibody." *Id.* Applicants respectfully traverse. However, as discussed above, Applicants have replaced the phrase "active ingredient chosen from an agonist or antagonist of binding to a PTH receptor or PTHrP receptor and a substance" in claim 1 with "humanized antibody."

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." M.P.E.P § 2131. Contrary to the Examiner's assertion, Grunfeld *et al.* does not disclose or teach humanized antibodies. Further, Applicants have canceled claims 2, 11, 15-17, 19-22, and 25, as discussed above, without prejudice or disclaimer, and therefore the rejection of these claims is moot. Applicants respectfully request that the Examiner withdraw the anticipation rejection of claims 1, 3, 9, 10, and 14.

OBJECTION TO THE CLAIMS

The Examiner objected to claims 1-3, 9-11, 14-17, 19-22, and 25 because the claims recite non-elected subject matter and claims 14-17 and 20 depend, in part, on non-elected claims. *See* Office Action at page 14. Applicants will consider amending the claims to overcome this objection once patentable subject matter has been indicated in this case. Until then, Applicants request that the Examiner hold the objection in abeyance.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully request the reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: November 18, 2004

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